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EXAMINER

CHIN, CHRISTOPHER L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,392

Applicant(s)

SMITH ET AL.

Examiner

Christopher L. Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/88)
Paper No(s)/Mail Date 6/28/07 and 11/7/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 27-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-29 are vague and indefinite. While the preambles of these claims are directed to "systems", the bodies of these claims recite steps for an assay. If it is Applicant's intent to claim a method of assay, then the claims should be amended accordingly. A "system" is analogous to a "kit" and thus should contain products/apparatus for detection of glycated albumin and total albumin. A "system" is not a method of assay.

Claim 32 is vague because it is not clear as to how the microparticles are related to the test strip. Claim 32 recites the test strip as being comprised microparticles. Is the test strip actually made of the microparticles?

Claim 35 suffers from the same deficiencies as claim 32.

Claim 44 is vague. Lines 12-15 are not clear as to which complexes are being referred to, those containing albumin or those containing glycated albumin.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 27-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8, 9, 11, 14, and 15 of copending Application No. 11/140,306. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending '306 claims a method for measuring glycated albumin compared to total albumin that uses a system with essentially the same limitations as the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Copending '306 claims an immunochromatographic procedure for measuring glycated albumin to total albumin in a saliva sample, wherein the procedure comprises the following steps:

(a) depositing the saliva sample in a sample well of a single test strip, the test strip comprising an application pad that filters out particulate material from the saliva sample and a membrane of material having a porosity that is selected to flow the

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remaining saliva sample filtrate along the test strip, wherein the test strip further comprises a mobile anti-albumin antibody band labeled with an indicator agent located distal to the sample well and wherein no other indicator agent is present on the test strip, a fixed band of glycated albumin binding reagent, and a fixed band of albumin binding reagent;

(b) allowing the saliva sample filtrate to migrate along the test strip; and

(c) measuring the intensity of the indicator agent at the fixed band of glycated albumin binding reagent band and at the fixed band of albumin binding reagent with a measuring instrument.

The measuring instrument is a reflectance spectrophotometer or fluorometer or other biosensor instrumentation that reads, calculates and displays the result as the percentage of glycated albumin compared to total albumin in the sample. The measuring instrument comprises the following element:

- a first means of measuring the fixed band of glycated albumin binding reagent;
- a second means of measuring the fixed band of albumin binding reagent;
- an internal computer chip for measurement and calculation;
- a liquid crystal display;
- an external port to transfer data to an external computer and/or printer;
- a battery and/or an external power source; and
- a rigid external case with an aperture for inserting the test strip.

The fixed bands for measuring glycated albumin and albumin read on the first and second assays recited in instant claim 27. The measuring instruments read on the means for calculating percent glycated albumin in the instant invention.

4. Claims 27-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 12, and 13 of copending Application No. 11/474,561. Although the conflicting claims are not identical, they are not patentably distinct from each other because .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Copending '561 claims an immunochromatographic procedure for measuring glycated albumin compared to total albumin in a blod sample, wherein the procedure comprises the following steps:

- (a) depositing the blood sample in a sample well of a single test strip, wherein the test strip further comprises a mobile anti-albumin antibody band labeled with an indicator agent located distal to the sample well, a fixed band of an anti-glycated protein chemical, and a fixed band of anti-albumin antibody;
- (b) allowing the blood sample to migrate along the test strip; and
- (c) measuring the label intensity at the fixed anti-glycated protein band and at the fixed anti-albumin band with a measuring instrument.

The measuring instrument is a reflectance spectrophotometer or other instrumentation that reads, calculates and displays the result as the percentage of

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glycated albumin compared to total albumin in the sample. The measuring instrument comprises the following element:

- a first means of measuring the fixed band of glycated albumin binding reagent;
- a second means of measuring the fixed band of albumin binding reagent;
- an internal computer chip for measurement and calculation;
- a liquid crystal display;
- an external port to transfer data to an external computer and/or printer;
- a battery and/or an external power source; and
- a rigid external case with an aperture for inserting the test strip.

The fixed bands for measuring glycated albumin and albumin read on the first and second assays recited in instant claim 27. The measuring instruments read on the means for calculating percent glycated albumin in the instant invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 27-31, 33, 38, 39, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al.

Yamamoto et al (EP 0 769 697 A1) discloses a method and dry test apparatus for simultaneously determining total albumin and glycated albumin. The test apparatus comprises (a) a support having thereon a developing layer; (b) blood cell separating layer; (c) a reagent layer containing albumin-staining dye (dye 1) and a glycated albumin staining dye (dye 2); (d) a measuring layer having fixed thereto an albumin-binding substance; and (e) a residual liquid absorbing layer. Parts (b)-(e) are arranged sequentially on the developing layer (col. 2, line 44, to col. 3, line 15). Figure 4A shows an embodiment of the apparatus where two separate test strips (2) and (2') are provided for measuring albumin and glycated albumin (col. 6, line 44, to col. 7, line 49). Albumin staining dye 1 can be a dye labeled anti-albumin antibody. Glycated albumin staining dye 2 can be a dye labeled anti-glycated albumin antibody. The anti-albumin and anti-glycated albumin antibodies can be either monoclonal or polyclonal antibodies (col. 9, lines 9-58). Figure 6 shows an embodiment where the apparatus includes a rigid housing that encloses 2 test strips. Albumin and glycated albumin with attached dye are detected on the test strips with equipment for photometry. A ratio of glycated albumin to albumin in a blood sample is calculated from the measurement (col. 5, lines 23-32).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 32 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al in view of Chudzik et al or Kang et al.

See above for the teachings of Yamamoto et al.

Yamamoto et al differs from the instant invention in failing to teach the use of particle labels instead of dyes to tag the anti-albumin and anti-glycated albumin antibodies.

Chudzik et al (US Patent 5,981,298) teaches the use of dyes or particles, such as colloidal metal particles or sol particle that are colored or colored polymeric particles, to label immunoreagents on test strips (col. 6, lines 51-65).

Kang et al (US Patent 5,559,041) teaches using metal sols, dye sols, or particulate latex as labels for tagging immunoreagents used on test strips (col. 8, lines 13-18).

It would have been obvious to one of ordinary skill in the art to substitute particle labels, as taught by Chudzik et al or Kang et al, for the dyes used by Yamamoto et al to label the anti-albumin and anti-glycated albumin antibodies because (1) Chudzik et al

shows that dyes and particle labels are functionally equivalent and interchangeable for labeling immunoreagents; and (2) Chudzik et al and Kang et al show that particle labels are well known and conventionally used in test strips.

10. Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al in view of Galen et al.

See above for the teachings of Yamamoto et al.

Yamamoto et al differs from the instant invention in failing to teach a reflectance spectrometer or fluorometer with the specific features recited in claims 40-43 to read their test strip.

Galen et al (US Patent 6,670,192 B1) discloses a method for measuring glycated albumin in a bodily fluid using a test strip and measuring instrument that measure albumin and glycated albumin. The measuring instrument comprises reflectance spectrometer with a first and second LEDs for measuring detection zones on the test strip, an internal computer chip for measurement and calculation, a liquid crystal display, an external port to transfer data, a battery power source, a rigid external case with an aperture for inserting a test strip, and memory for storing test results (cols. 13-14).

It would have been obvious to one of ordinary skill in the art to use the spectrometer of Galen et al to read the test strip of Yamamoto et al because Yamamoto et al specifically teaches using a spectrometer to read their test strip and Galen et al specifically teaches using their spectrometer to read test strips, like those of Yamamoto et al, that are for detecting albumin and glycated albumin.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher L. Chin/
Primary Examiner, Art Unit 1641

6/21/08